

EC DECLARATION OF CONFORMITY

(Class IIB Product)

Z-Medica, LLC declares that the gamma-sterilized Kaolin based QuikClot® medical device product family, specified in the product list below, is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC.

Kaolin Based QuikClot®
Related Products in the Same Product Family

Description	Packaged Quantity	Catalog No.
QuikClot® Interventional Hemostatic Bandage™ CE – English, n/slit with 3M Tegaderm –Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM)	Ten (10) per box	183
QuikClot® Interventional Hemostatic Bandage™ CE- English Language, pre-slit with 3M Tegaderm - Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM)	Ten (10) per box	188
QuikClot® Combat Gauze Z-Fold Vacuum Pack - English Language, One (1) Sterile Gauze Z-Fold Strip 3 IN x4 YDS (7.5CM x 3.7M)	Sold individually	200
QuikClot® Combat Gauze Z-Fold Vacuum Pack - Polish Language, One (1) Sterile Gauze Z-Fold Strip 3 IN x4 YDS (7.5CM x 3.7M)	Sold individually	200-PL
QuikClot® Combat Gauze TraumaPad Vacuum Pack™ CE- English Language, One (1) Sterile, X-Ray Detectable Hemostatic Dressing 12 IN x 12 IN (30.0CM x 30.0CM)	Sold individually	210
QuikClot® Gauze™, CE, German,7.5cmX3.7m, Z-Fold, V-Pack, One (1) Sterile Gauze Z-Fold Strip 3 IN x 4 YDS (7.5CM X 3.7M)	Sold individually	289
QuikClot® 2x2 Hemostatic Dressing™, Multi-Language, CE, Sterile Gauze Dressing 2 IN x 2 IN (5 CM X 5 CM) – Identical to US version PN 458	Ten (10) per box	302
QuikClot® 4 x 4 Hemostatic Dressing™, CE, Multi-Language, XR, Ten (10) Sterile Gauze Sponge 4 IN x 4 IN (10 CM x 10 CM) – Identical to US version PN 459	Ten (10) per box	301
QuikClot® TraumaPad™ CE- Multi-Language, Ten (10) Sterile, Double Wrapped, X-Ray Detectable Hemostatic Dressing 12 IN x 12 IN (30 CM x 30 CM) – Identical to US version PN 460	Ten (10) per box	303
QuikClot® Combat Gauze XL, Z-Folded and Vacuum Packed – CE- English Language, One (1) Sterile Gauze Z-Fold Strip 2-ply 4” x 4 yards (10.2 CM x 3.7M)	Sold individually	345
QuikClot® Combat Gauze LE, Z-Fold Vacuum Pack - English Language, One (1) Sterile Gauze Z-Fold Strip 3 IN x4 YDS (7.5CM x 3.7M)	Sold individually	350
QuikClot® Radial Hemostatic Bandage™, CE, English, with WJB Direct Pressure (DP) Dressing - Sterile Gauze Pad 0.8" D x 1.5" L (2cm dia x 3.8 CM)	Ten (10) per box	374
QuikClot® Interventional Hemostatic Bandage™ CE – English, n/slit –Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM)	Ten (10) per box	467-Z
QuikClot® EMS 4x4 Dressing, no x-ray, , CE – English Language	Three (3) per bag	473

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(Class IIb Product)

QuikClot® EMS Rolled Gauze 3" x 4 ft (7.6cm x 1.2m), CE – English Language	Sold individually	475
QuikClot® Z-Fold Hemostatic Dressing - English Language, ten (10) Sterile Gauze Z-Fold Strip 3 IN x4 YDS (7.6CM x 3.7M)	Ten (10) per box	632
QuikClot® Roll Hemostatic Dressing - English Language, ten (10) Sterile Gauze Roll 3 IN x4 YDS (7.6CM x 3.7M)	Ten (10) per box	633

and is in conformity with the following international quality standards:

EN 1041:2008 / A1:2013
AAMI ST67:2011 / R2017
ISO 11137:2006 / A1:2013
AAMI ISO 11607-1:2019

ISO 15223-1:2016
ISO 13485:2016
ISO 10993-1:2018
BS EN ISO 14971:2012

is represented, for regulatory affairs only, by an Authorized Representative in Europe:



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is subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of which is the subject of **CE Cert# 508609** issued by Notified Body Number 2797, BSI Group The Netherlands BV, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

A handwritten signature in black ink, appearing to read 'Joseph Azary'.

4 Fairfield Blvd.
Wallingford, Connecticut 06492
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Place and date of issue

Joseph Azary, VP, Quality & Regulatory